

REMARKS/ARGUMENTS

Reconsideration and allowance of the above-referenced application are respectfully requested.

Claim 2 has been amended as well as the specification.

Further, the Examiner is requested to note that the Preliminary Amendment of June 4, 2002 included the insertion of sequence identifier numbers, in the Brief Description of the Drawings section, in connection with the sequences presented in Figures 18A and 18B. Additionally, the description of Figure 16 has been amended herein to include a corresponding sequence identifier number.

Rejection of Claims 2-4 Under 35 U.S.C. 112, Second Paragraph

The Examiner has rejected claims 2-4 under Section 112, second paragraph as failing to comply with the written description requirement. In particular, the Examiner contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors, at the time the application was filed, had possession of the claimed invention. More specifically, the Examiner asserts that this is a new matter rejection.

In response, Applicants submit that support for the amendments to claims 2-4 included in the Amendment filed on January 15, 2004 may be supported, for example, by Example 10 on page 91 of the specification. In particular, on page 91, lines 31-33 of the specification, the inventors state that “[W]hile no one of the markers efficiently detects *all* breast cancers, a combination of two or more may achieve a very high sensitivity in assays for circulating or occult breast cancer cells.” Further, on page 93, lines 18-20, the

inventors state “[N]ot all cancers express each marker indicating that a combination of two or more of these markers will be needed to detect all breast cancers.”

In view of the above, it is respectfully submitted that the Section 112, first paragraph rejection of claims 2-4 has been overcome and should be withdrawn accordingly.

Rejection of Claim 2 Under 35 U.S.C. 112, First Paragraph

The Examiner has rejected claim 2 under Section 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner contends that claim 2 recites an incomplete method step.

In response, it is submitted that the Examiner’s concerns have been adequately addressed by the amendment to claim 2 noted above. Thus, it is respectfully requested that the Section 112, second paragraph rejection be withdrawn.

Rejection of Claims 2-4 Under 35 U.S.C. 103(a)

The Examiner has rejected claims 2-4 under Section 103(a) as being obvious over U.S. Patent Application Publication No. 2002/0009738 (Houghton et al.). In particular, the Examiner alleges that it would have been *prima facie* obvious to the skilled artisan at the time the invention was made to utilize antibodies in the detection of the taught breast tumor proteins in a patient sample within a tissue section or cell culture.

In response, Applicants respectfully traverse the rejection. In particular, it is submitted that the Houghton et al. document discloses the identification of tissue-specific polynucleotides and methods for determining the presence of cancer in a patient by detecting polynucleotides which encode breast tumor proteins. It must be noted,

however, that the polynucleotides of the Houghton et al. document do not necessarily encode expressed proteins. In particular, there are many polynucleotides which are never translated and therefore a corresponding encoded polypeptide may not be detected either in tissue or in the circulation. (References relating to mRNA which is not translated into an encoded protein may be provided if the Examiner so desires.) Thus, the Examiner's statement that "It would follow that the detection of encoded polypeptides would be useful in the diagnosis of breast cancer" is not accurate, as some polynucleotides do not result in detectable, encoded proteins.

In contrast to Houghton et al., the claimed invention relates to the detection of actual polypeptide markers (or complexes thereof) present in specific combinations. Presence of the specific combination of proteins or presence of antibody-antigen complexes of each protein of a combination is indicative of a diagnosis of breast cancer. One is not utilizing polynucleotides in any manner. One is utilizing only the presence of combinations of expressed proteins markers or complexes including the markers. Thus, the presently claimed invention is quite distinct from the teachings and suggestions of Houghton et al. The polynucleotides of Houghton et al. would not have motivated one of ordinary skill in the art to utilize the polypeptide markers of the present invention much less in the combinations recited in the claims.

Further, it should also be noted that MPA, BU101 and BS106 (utilized in the methods of the present invention) are neither disclosed nor suggested in the Houghton et al. document nor are the specific combinations of polypeptide markers of the claimed invention, as noted above.

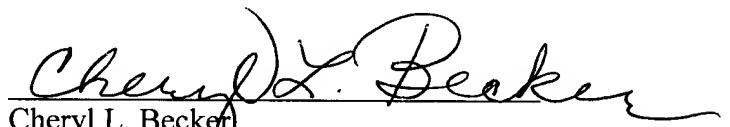
In view of the above, it is submitted that one of ordinary skill in the art certainly would not have been motivated to have created the claimed invention based upon the teachings and suggestions of Houghton et al. The Section 103 rejection has been overcome and should be withdrawn accordingly.

In conclusion, it is believed that the subject application is in condition of allowance and Notice to that effect is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,
J. Henslee, et al.

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